BSI-495US1 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Darragh Colgan et al.	: Art Unit:
Serial No.:	To Be Assigned	: Examiner:
Filed:	Herewith	:
For:	STENT DELIVERY SYSTEM	:

Divisional of:

Applicant:	Darragh Colgan et al.	: Art Unit:	3731
Serial No.:	09/270,949	: Examiner:	V. Bui
Filed:	March 17, 1999	:	
FOR:	STENT DELIVERY SYSTEM	:	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

S I R :

Prior to examination, please amend the above-identified application as follows:

IN THE SPECIFICATION:

Please replace the paragraph beginning at page 1, line 1, with the following:

This application is a divisional of application number 09/270,949, filed March 19, 1999 (allowed), which is a continuation-in-part of United States Patent Application Number 09/052,214, filed on March 31, 1998, the entire teachings of which are incorporated herein by reference.

Please replace the paragraph beginning at page 16, line 26 with the following:

In addition, the stent 10 can be introduced using a percutaneous insertion. In both the method using the endoscope 70 and the percutaneous procedure, an over the wire delivery system 86 as seen in FIG. 6A can be used. The over-the-wire delivery system 86 has an elongated catheter on inner shaft 88 over which the stent 10 is positioned. The shaft 88 extends from a proximal handle 90 to a distal tip end 92. The shaft 88 extends through an outer shaft 94 at the proximal end.

Please replace the paragraph beginning at page 18, line 24 with the following:

An alternative method to the over-the-wire delivery system 86 shown in FIGS. 6A and 6B is a rapid exchange delivery system 112 shown in FIG. 7. The rapid exchange delivery system 112 has a shaft 114 that extends from a proximal handle 116. A guidewire 118 extends from a two lumen transition zone 120 through an outer sheath 122 to a distal tip end 124. In contrast to the over the wire delivery system 86, the guide wire 118 does not extend all the way back to the proximal handle 116. Similar to the over the wire delivery system 86, the outer sheath 122 of the rapid exchange delivery system 112 is moved towards the handle 116 using a pull wire 128 and a pull ring 130.

Please replace the paragraph beginning at page 19, line 19 with the following:

Referring to FIG. 6A, the delivery system 86 is advanced axially and distally until the distal radiopaque marker 140 is positioned axially at a location at least about 1 cm distal of the occlusion 134. This location substantially corresponds to the position at which the distal end 47 of the stent 10, when expanded, will engage the lumen wall 136. The location is selected so the stent 10 is positioned beyond the occlusion 134 but not too close to the end of the bile duct, for example. The marker 138 indicates the position of the proximal end 40 of the stent 10 in the expanded position and is such that the proximal end 40 of the prosthesis will engage healthy tissue over a length of at least 1 cm. Where possible the stent 10 is centered about the obstruction, based on the fully expanded length indicated by markers 138 and 140. The marker 139 indicates the proximal end of the stent when the stent is in the fully compact form, which has an overall length of approximately 20 percent longer than in its expanded state. Therefore for a stent of 7.5 centimeters, the compressed state has a length of approximately 9 centimeters.

Please replace the paragraph beginning at page 27, line 24 with the following:

Within the inner shaft 288 a guidewire 312 may extend as seen in FIG. 16A. The guidewire 312 in a preferred embodiment is formed of stainless steel. The guidewire 312 in a preferred embodiment has a diameter in the range of

0.014 to 0.037 inches (0.36 to 0.94 mm) and in a preferred embodiment 0.035 inches (0.89 mm)

Please replace the paragraph beginning at page 32, line 11 with the following:

The outer sheath 382 is formed of a plurality of layers. An inner layer 390 is formed of a fluorinated polymer such as PTFE or FEP, or polymer such as HDPE. A second layer 392 (shown in FIG. 20B) encases the first layer and consists of a polyurethane such as those sold underneath the name TECOFLEX™ or PLEXAR™. A third layer 394 consists of a polymer braiding, such as LCP fiber (Vectran), or a metal braided coil. In a preferred embodiment, the braiding is flat. However, it is recognized that a round braiding may also be used. A fourth layer 398, an outer layer, of the outer sheath 382 material properties vary as it goes from the proximal end to the distal end.

IN THE CLAIMS:

Please cancel claims 1-5, and 10-20.

Please amend claim 6 to read as follows:

6. A stent delivery system comprising:

a catheter having an inner shaft with a distal end and a proximal end;

an outer shaft disposed around the inner shaft, wherein the outer shaft is moveable relatively to the inner shaft;

a handle attached to the proximal end of the catheter;

a stent concentrically arranged around a distal region of the inner shaft, wherein a guidewire is disposed within a lumen of the inner shaft; and

a sheath extending around the inner shaft and the stent, the sheath having a composite structure and being coupled to an actuator on the handle with a wire such that the sheath can be moved longitudinally relative to the inner shaft in response to the movement of the actuator;

wherein said stent comprises a tubular body having a plurality of strands helically wrapped about each other to form spaced interlocking joints.

Please amend claim 9 to read as follows:

9. The stent delivery system of Claim 6 further comprising a mounting ring having longitudinal ridges that hold the stent to a stent platform during mounting of the stent to the inner shaft.

DRAWINGS:

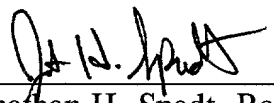
Please amend FIG. 6A as indicated in red on the enclosed copy of FIG. 6A.

Please amend FIG. 20A as indicated in red on the enclosed copy of FIG. 20A.

REMARKS

Claims 6-9 and 21-40 are now pending for consideration.

Respectfully Submitted,



Jonathan H. Spadt, Reg. No.45,122
Attorneys for Applicants

JHS/mkm
Dated: January 14, 2002
Suite 301
One Westlakes, Berwyn
P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

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I hereby certify that this paper and fee are being deposited, under 37 C.F.R. § 1.10 and with sufficient postage, using the "Express Mail Post Office to Addressee" service of the United States Postal Service on the date indicated above and that the deposit is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Kathleen Libby

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

This application is a divisional of application number 09/270,949, filed March 19, 1999 (allowed), which is a continuation-in-part of United States Patent Application Number 09/052,214, filed on March 31, 1998, the entire teachings of which are incorporated herein by reference. ~~This application is a continuation-in-part of United States Patent Application Number 09/052,214, filed on March 31, 1998, the entire teachings of which are incorporated herein by reference.~~

Specification at page 16, line 26

In addition, the stent 10 can be introduced using a percutaneous insertion. In both the method using the endoscope 70 and the percutaneous procedure, an over the wire delivery system 86 as seen in FIG. 6A can be used. The over-the-wire delivery system 86 has an elongated catheter on inner ~~shift~~ shaft 88 over which the stent 10 is positioned. The ~~catheter~~ shaft 88 extends from a proximal handle 90 to a distal tip end 92. The ~~catheter~~ shaft 88 extends through an outer shaft 94 at the proximal end.

Specification at page 18, line 24.

An alternative method to the over-the-wire delivery system 86 shown in FIGS. 6A and 6B is a rapid exchange delivery system 112 shown in ~~S~~FIG. 7. The rapid exchange delivery system 112 has a shaft 114 that extends from a proximal handle 116. A guidewire 118 extends from a two lumen transition zone 120 through an outer sheath 122 to a distal tip end 124. In contrast to the over the wire delivery system 86, the guide wire 118 does not extend all the way

back to the proximal handle 116. Similar to the over the wire delivery system 86, the outer sheath 122 of the rapid exchange delivery system 112 is moved towards the handle 116 using a pull wire 128 and a pull ring 130.

Specification at page 19, line 19.

Referring to FIG. 6A, the delivery system 86 is advanced axially and distally until the distal radiopaque marker ~~60~~140 is positioned axially at a location at least about 1 cm distal of the occlusion 134. This location substantially corresponds to the position at which the distal end 47 of the stent 10, when expanded, will engage the lumen wall 136. The location is selected so the stent 10 is positioned beyond the occlusion 134 but not too close to the end of the bile duct, for example. The marker 138 indicates the position of the proximal end 40 of the stent 10 in the expanded position and is such that the proximal end 40 of the prosthesis will engage healthy tissue over a length of at least 1 cm. Where possible the stent 10 is centered about the obstruction, based on the fully expanded length indicated by markers 138 and 140. The marker 139 indicates the proximal end of the stent when the stent is in the fully compact form, which has an overall length of approximately 20 percent longer than in its expanded state. Therefore for a stent of 7.5 centimeters, the compressed state has a length of approximately 9 centimeters.

Specification at page 27, line 24.

Within the ~~single braided polymer tube~~inner shaft 288 a guidewire ~~326~~312 may extend as seen in FIG. 16A. The guidewire ~~326~~312 in a preferred

embodiment is formed of stainless steel. The guidewire ~~326~~312 in a preferred embodiment has a diameter in the range of 0.014 to 0.037 inches (0.36 to 0.94 mm) and in a preferred embodiment 0.035 inches (0.89 mm)

Specification at page 32, line 11.

The outer sheath 382 is formed of a plurality of layers. An inner layer 390 is formed of a fluorinated polymer such as PTFE or FEP, or polymer such as HDPE. A second layer 392 (shown in FIG. 20B) encases the first layer and consists of a polyurethane such as those sold underneath the name TECOFLEX™ or PLEXAR™. A third layer 394 consists of a polymer braiding, such as LCP fiber (Vectran), or a metal braided coil. In a preferred embodiment, the braiding is flat. However, it is recognized that a round braiding may also be used. A fourth layer 398, an outer layer, of the outer sheath 382 material properties vary as it goes from the proximal end to the distal end.

IN THE CLAIMS:

6. ~~The stent delivery system of Claim 1 wherein the stent comprises a tubular body having a plurality of strands being helically wrapped about each other to form spaced interlocking joints.~~A stent delivery system comprising:

a catheter having an inner shaft with a distal end and a proximal end;

an outer shaft disposed around the inner shaft, wherein the outer shaft is moveable relatively to the inner shaft;

a handle attached to the proximal end of the catheter;

a stent concentrically arranged around a distal region of the inner shaft, wherein a guidewire is disposed within a lumen of the inner shaft; and

a sheath extending around the inner shaft and the stent, the sheath having a composite structure and being coupled to an actuator on the handle with a wire such that the sheath can be moved longitudinally relative to the inner shaft in response to the movement of the actuator;

wherein said stent comprises a tubular body having a plurality of strands helically wrapped about each other to form spaced interlocking joints.

9. The stent delivery system of Claim ~~1~~6 further comprising a mounting ring having longitudinal ridges that hold the stent to a stent platform during mounting of the stent to the inner shaft.